NOVARTIS

Clinical Trial Results Website

Sponsor

Novartis Pharmaceuticals

Generic Drug Name

Secukinumab

Trial Indication(s)

Plaque psoriasis

Protocol Number

CAIN457A2317

Protocol Title

A 52-week, multicenter, randomized, double-blind study of
subcutaneous secukinumab to demonstrate efficacy as
assessed by Psoriasis Area and Severity Index at 16 weeks of treatment compared to ustekinumab and to assess long-term safety, tolerability and efficacy in subjects with moderate to severe plaque psoriasis (CLEAR)

Clinical Trial Phase

Phase 3

Phase of Drug Development

Phase 3b

Study Start/End Dates

Study Start Date: February 2014 (Actual)
Primary Completion Date: June 2016 (Actual)

Study Completion Date: June 2016 (Actual)

Reason for Termination (If applicable)

Study Design/Methodology

This was a multicenter, randomized, double-blind, comparator-controlled, parallel group superiority trial in patients with moderate to severe plaque psoriasis. The study consisted of four epochs: the screening epoch, the treatment epoch 1 (treatment period 1), treatment epoch 2 (treatment period 2) and treatment epoch 3 (treatment period 3). The screening epoch (1 - 4 weeks) was used to assess the patient's eligibility and to taper patients off prohibited medications. The treatment epoch 1 was the period between randomization and Week 16 prior to dosing. At the start of the treatment epoch 1, eligible patients were randomized in a 1:1 ratio to one of the two treatment arms (secukinumab or ustekinumab). The dose of ustekinumab was determined by the patient's body weight at baseline: patients with body weight ≤100 kg at baseline received ustekinumab 45 mg sc and patients with body weight >100 kg at baseline received ustekinumab 90 mg sc. Randomization into the two treatment arms was stratified by body weight at baseline (≤100 kg and >100 kg). All patients attended study visits at randomization (baseline) and at Weeks 1, 2, 3, and 4, and at 4-week intervals from Week 4 to Week 16 (pre-dose assessments).

- Secukinumab arm patients received secukinumab 300 mg sc (two secukinumab 150 mg injections sc) weekly at randomization, Week 1, Week 2, Week 3, and Week 4 and at 4-weeks intervals from Week 4 to Week 12.
- Ustekinumab arm patients received ustekinumab sc (45 mg or 90 mg of ustekinumab according to body weight at baseline) at randomization and at Week 4. In addition, in order to maintain the blind, placebo injections were given, so that all patients in the study receive two injections at each dosing visit.

All assessments for the primary endpoint were done at Week 16 for all treatment arms prior to the dose at Week 16. Patients who completed the treatment epoch 1 entered the treatment epoch 2. For patients who discontinued study treatment prematurely for any reason before the end of the treatment epoch 1 (other than withdrawal of informed consent and lost to follow up), the Week 16 visit (planned end of treatment epoch 1 [EOT1] visit) was to be performed approximately 4 weeks after their last dose of study treatment.

The treatment epoch 2 was the period from the Week 16 dose onwards to Week 52 (pre-dosing), with patients attending study visits at 4-week intervals from Week 16 to Week 52, inclusive. During the treatment epoch 2, patients were treated with the dosing regimen according to the following schedule:

- Secukinumab arm continued to receive secukinumab 300 mg sc (two secukinumab 150 mg injections sc) at 4-week intervals from Week 16 to Week 48 (inclusive)
- Ustekinumab arm continued to receive ustekinumab (45 mg or 90 mg ustekinumab according to body weight at baseline) sc at Week 16, Week 28, and Week 40. In addition, in order to maintain the blind, placebo injections matching secukinumab sc injections were given, so that all patients in the study received 2 injections at each dosing visit.

Patients who completed the treatment epoch 2 per protocol and who did not consent to have had their treatment extended in treatment epoch 3 received the last dose of investigational treatment at Week 48 and came for their end of treatment epoch 2 [EOT2] visit at Week 52.
For all patients who discontinued study treatment prematurely for any reason before the end of the treatment epoch 2 (other than withdrawal of informed consent and lost to follow up), the Week 52 visit (planned end of treatment epoch 2 [EOT2] visit) was to be performed approximately 4 weeks after their last dose of study treatment (secukinumab or ustekinumab).
Patients who completed the treatment epoch 2 and have had consented to continue in the study entered the treatment epoch 3 and received their first dose at Week 52.
During the treatment epoch 3, all patients attend study visits at 4-week intervals.
All patients were treated in a blinded fashion until Week 52 database lock.
At time of Week 52 database lock, patients were at different stages of the study (approximately between Week 64 and Week 80).
After Week 52 database lock data was unblinded and:

- Patients on ustekinumab attended end of treatment epoch 3 (EOT3) marking end of the study participation (approximately 4 weeks after the last dosing in the study). For example, if last dosing was at visit Week 60 for a particular ustekinumab patient and Week 52 database lock (16-Sep-2015) occurred between Week 60 and Week 64, Week 64 became EOT3 for that patient. Blinded investigators were notified that Week 52 database lock had occurred on 16-Sep-2015. In this example, when the pharmacist made the Interactive Randomization Technology (IRT) call at Week 64, the patient was notified there was no dosing at Week 64 as the patient was in the ustekinumab arm and the blinding was opened. This patient would then be updated in the system as completed and treated as per standard of care outside of the study. Hence for ustekinumab patients the total duration of the study varied approximately from 64 to 80 weeks.
- Patients on secukinumab entered in the open label arm of the study to receive secukinumab 300 mg, at 4-weeks intervals until Week 100 and had the EOT3 at Week 104 or until the drug became commercially available.

Centers

134 centers in 24 countries: Australia (4) centers, Austria (4) centers, Belgium (3) centers, Bulgaria (4) centers, Canada (4) centers, Denmark (1) center, Estonia (2) centers, France (4) centers, Germany (23) centers, Greece (1) center, Hungary (2) centers, Israel (3) centers, Italy (2) centers, Korea (3) centers, Netherlands (5) centers, Norway (1) center, Portugal (5) centers, Slovakia (4) centers, Spain (20) centers, Switzerland (1) center, Taiwan (2) centers, Turkey (2) centers, United Kingdom (8) centers, United States (26) centers

Objectives:

The primary objective of this study was to demonstrate the superiority of secukinumab compared to ustekinumab in patients with moderate to severe plaque psoriasis based on the proportion of Psoriasis Area and Severity Index (PASI) 90 responders at Week 16.
The secondary objectives of the study were to demonstrate:

- the superiority of secukinumab versus ustekinumab as to the speed of onset based on the proportion of patients achieving PASI 75 at Week 4.
- the superiority of secukinumab versus ustekinumab based on the proportion of PASI 90 responders at Week 52.

Test Product (s), Dose(s), and Mode(s) of Administration

Secukinumab 300 mg s.c. (subcutaneous) injection

Placebo Secukinumab s.c. (subcutaneous) injection

Ustekinumab 45 mg or 90 mg (depending on weight) s.c. (subcutaneous) injection

Statistical Methods

The family-wise error was set to α=5% (two-sided). The primary objective H1 was tested at α (twosided). The secondary objectives H2 and H3 were tested sequentially and were included in the hierarchical testing strategy and type-I-errors set such that a family-wise type-I-error of 5% was kept.
Both of the primary analysis and the secondary analysis method were evaluated using a logistic regression model with treatment group, randomized strata, and baseline PASI score as explanatory variables. Odds ratios were computed for comparisons of secukinumab versus ustekinumab utilizing the logistic regression model fitted. In case of non-convergence, Fisher's exact test was performed.
The non-responder imputation method was used as primary method for missing data; multiple imputation was planned as secondary method; for the long-term sustainability (after week 52), the as observed results were provided primarily and

multiple imputation method as supportive method. Last observation carried forward (LOCF) method was used for the patient-reported outcomes (PROs).
Treatment-emergent AEs (events started after the first dose of study medication or events present prior to the first dose of study medication but increased in severity based on preferred term and started prior to the last dose plus 84 days (inclusive)). AEs were summarized by presenting for each treatment group the number and percentage of patients having any AE, having an AE in each primary system organ class (SOC), and having each individual AE (preferred term). Summaries were also presented for AEs by severity and for study treatment-related AEs. Separate summaries were provided for death, SAEs, other significant AEs leading to discontinuation, and AEs leading to study treatment discontinuation. Due to different exposure duration planned for the treatment arms, the exposure adjusted incidence rates were used to explain the safety result.
The summary of laboratory evaluations was presented for two groups of laboratory tests (hematology and serum chemistry). Descriptive summary statistics for the change from baseline to each study visit were presented by laboratory test group, laboratory parameters and treatment group. In addition, laboratory parameters were analyzed with respect to Common Terminology Criteria for Adverse Events (CTCAE) grades. Newly occurring liver enzymes abnormalities were also summarized.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:
- patients with moderate to severe plaque type psoriasis for at least 6 months before randomization
- patients eligible for systemic therapy with inadequately controlled psoriasis

Exclusion Criteria:
- forms of sporiasis other than plaque type psoriasis
- previous exposure to secukinumab, ustekinumab, or other biologic drugs targeting (IL)-17A or IL-17RA

Other protocol-defined inclusion/exclusion criteria may apply

Participant Flow Table

Overall Study

	AIN457 300 mg	Ustekinumab
Started	337	339
Full Analysis Set (FAS)	336	339
Safety Set (SF)	335	336
Completed	286	285
Not Completed	51	54
Adverse Event	15	7
Lack of Efficacy	6	1
Lost to Follow-up	9	10
Non-compliance with study treatment	0	2
Physician Decision	1	1
Pregnancy	1	2
Protocol deviation	4	3
Technical problems	0	2
Subject/guardian decision	15	24
Death	0	2

Baseline Characteristics

	AIN457 300 mg	Ustekinumab	Total
Number of Participants [units: participants]	337	339	676
Age Continuous (units: years) Mean ± Standard Deviation	45.2±13.95	44.6±13.67	44.9±13.81
Gender, Male/Female (units: participants)			
Female	108	87	195
Male	229	252	481

Summary of Efficacy

Primary Outcome Result(s)

Percentage of participants with moderate to severe plaque psoriasis who achieved Psoriasis Area and Severity Index (PASI) 90 at Week 16

	AIN457 300 mg	Ustekinumab
Number of Participants Analyzed [units: participants]	334	335
Percentage of participants with moderate to severe plaque psoriasis who achieved Psoriasis Area and Severity Index (PASI) 90 at Week 16 (units: Percentage of Participants)	79.0	57.3

Statistical Analysis

Groups	AIN457 300 mg, Ustekinumab
Non-Inferiority/Equivalence Test	No
P Value	<0.0001
Method	Regression, Logistic
Odds Ratio (OR)	2.85

95 % Confidence Interval 2-Sided	2.01 to 4.02

Secondary Outcome Result(s)

Speed of onset based on the Percentage of participents achieving PASI 75 at Week 4

	AIN457 300 mg	Ustekinumab
Number of Participants Analyzed [units: participants]	334	335
Speed of onset based on the Percentage of participents achieving PASI 75 at Week 4 (units: percentage of participants)	49.7	20.6

Percentage of participants with moderate to severe plaque psoriasis who achieved Psoriasis Area and Severity Index (PASI) 90 at Week 52

	AIN457 300 mg	Ustekinumab
Number of Participants Analyzed [units: participants]	334	335
Percentage of participants with moderate to severe plaque psoriasis who achieved Psoriasis Area and Severity Index (PASI) 90 at Week 52 (units: percentage of participants)	74.9	60.6

Summary of Safety

Safety Results

Serious Adverse Events by System Organ Class

Time Frame	Adverse events are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All adverse events reported in this record are from date of First Patient First Treatment until Last Patient Last Visit.

Source Vocabulary for Table Default	MedDRA (19.0)
Assessment Type for Table Default	Systematic Assessment

	AIN457 300 mg N = 335	Ustekinumab N = 336
Total participants affected	41 (12.24%)	32 (9.52%)
CARDIAC DISORDERS		
ANGINA UNSTABLE	0 (0.00%)	1 (0.30%)
ATRIAL FIBRILLATION	1 (0.30%)	0 (0.00%)
ATRIAL FLUTTER	1 (0.30%)	0 (0.00%)
MYOCARDIAL INFARCTION	0 (0.00%)	1 (0.30%)
VENTRICULAR FAILURE	1 (0.30%)	0 (0.00%)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS		
HAMARTOMA	0 (0.00%)	1 (0.30%)
EAR AND LABYRINTH DISORDERS		
TYMPANIC MEMBRANE PERFORATION	1 (0.30%)	0 (0.00%)
EYE DISORDERS		
OCULAR HYPERTENSION	1 (0.30%)	0 (0.00%)

VITREOUS ADHESIONS	0 (0.00%)	1 (0.30%)
GASTROINTESTINAL DISORDERS		
DIARRHOEA	1 (0.30%)	0 (0.00%)
INGUINAL HERNIA	0 (0.00%)	1 (0.30%)
NAUSEA	0 (0.00%)	1 (0.30%)
PANCREATITIS ACUTE	1 (0.30%)	0 (0.00%)
VOMITING	0 (0.00%)	1 (0.30%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		
DEATH	0 (0.00%)	1 (0.30%)
GENERAL PHYSICAL HEALTH DETERIORATION	1 (0.30%)	0 (0.00%)
SYSTEMIC INFLAMMATORY RESPONSE SYNDROME	1 (0.30%)	0 (0.00%)
HEPATOBILIARY DISORDERS		
CHOLECYSTITIS	1 (0.30%)	1 (0.30%)
CHOLELITHIASIS	1 (0.30%)	0 (0.00%)
CIRRHOSIS ALCOHOLIC	1 (0.30%)	0 (0.00%)
DRUG-INDUCED LIVER INJURY	1 (0.30%)	0 (0.00%)
HEPATITIS ACUTE	1 (0.30%)	0 (0.00%)
NON-ALCOHOLIC FATTY LIVER	1 (0.30%)	0 (0.00%)

INFECTIONS AND INFESTATIONS		
ABSCESS	0 (0.00%)	1 (0.30%)
ABSCESS LIMB	1 (0.30%)	0 (0.00%)
APPENDICITIS	1 (0.30%)	0 (0.00%)
DIVERTICULITIS	0 (0.00%)	1 (0.30%)
ERYSIPELAS	0 (0.00%)	1 (0.30%)
ESCHERICHIA URINARY TRACT INFECTION	1 (0.30%)	0 (0.00%)
LARYNGITIS	1 (0.30%)	0 (0.00%)
NASAL ABSCESS	1 (0.30%)	0 (0.00%)
ORAL CANDIDIASIS	1 (0.30%)	0 (0.00%)
PILONIDAL CYST	0 (0.00%)	1 (0.30%)
PNEUMONIA	1 (0.30%)	0 (0.00%)
SCROTAL ABSCESS	0 (0.00%)	1 (0.30%)
SEPTIC SHOCK	0 (0.00%)	1 (0.30%)
SUBCUTANEOUS ABSCESS	0 (0.00%)	1 (0.30%)
TONSILLITIS	0 (0.00%)	1 (0.30%)
VIRAL UPPER RESPIRATORY TRACT INFECTION	1 (0.30%)	0 (0.00%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		
ALCOHOL POISONING	1 (0.30%)	0 (0.00%)
CONCUSSION	1 (0.30%)	0 (0.00%)
FIBULA FRACTURE	1 (0.30%)	0 (0.00%)

FOOT FRACTURE	1 (0.30%)	0 (0.00%)
HAND FRACTURE	0 (0.00%)	1 (0.30%)
HUMERUS FRACTURE	0 (0.00%)	1 (0.30%)
INJECTION RELATED REACTION	0 (0.00%)	1 (0.30%)
JAW FRACTURE	1 (0.30%)	0 (0.00%)
LOWER LIMB FRACTURE	1 (0.30%)	0 (0.00%)
POST CONCUSSION SYNDROME	1 (0.30%)	0 (0.00%)
RADIUS FRACTURE	1 (0.30%)	0 (0.00%)
INVESTIGATIONS		
ALANINE AMINOTRANSFERASE INCREASED	1 (0.30%)	1 (0.30%)
ASPARTATE AMINOTRANSFERASE INCREASED	0 (0.00%)	2 (0.60%)
BLOOD BILIRUBIN INCREASED	1 (0.30%)	0 (0.00%)
HEPATIC ENZYME INCREASED	1 (0.30%)	0 (0.00%)
METABOLISM AND NUTRITION DISORDERS		
HYPONATRAEMIA	1 (0.30%)	0 (0.00%)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		
ARTHRALGIA	0 (0.00%)	1 (0.30%)
BACK PAIN	0 (0.00%)	1 (0.30%)

OSTEOARTHRITIS	1 (0.30%)	1 (0.30%)
ROTATOR CUFF SYNDROME	0 (0.00%)	1 (0.30%)
SPINAL PAIN	0 (0.00%)	1 (0.30%)
TENDONITIS	0 (0.00%)	1 (0.30%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		
BASAL CELL CARCINOMA	1 (0.30%)	0 (0.00%)
BRAIN NEOPLASM BENIGN	0 (0.00%)	1 (0.30%)
FIBROADENOMA OF BREAST	1 (0.30%)	0 (0.00%)
HAEMANGIOMA OF LIVER	0 (0.00%)	1 (0.30%)
KERATOACANTHOMA	1 (0.30%)	0 (0.00%)
LUNG ADENOCARCINOMA	1 (0.30%)	0 (0.00%)
MALIGNANT MELANOMA IN SITU	2 (0.60%)	0 (0.00%)
NERVOUS SYSTEM DISORDERS		
AMNESIA	1 (0.30%)	0 (0.00%)
CAROTID ARTERY DISEASE	1 (0.30%)	0 (0.00%)
CARPAL TUNNEL SYNDROME	0 (0.00%)	1 (0.30%)
CEREBRAL HAEMORRHAGE	1 (0.30%)	0 (0.00%)

EMBOLIC STROKE	1 (0.30%)	0 (0.00%)
FACIAL PARESIS	1 (0.30%)	0 (0.00%)
FACIAL SPASM	1 (0.30%)	0 (0.00%)
HEADACHE	1 (0.30%)	0 (0.00%)
POSTICTAL PARALYSIS	1 (0.30%)	0 (0.00%)
SYNCOPE	0 (0.00%)	1 (0.30%)
TRANSIENT ISCHAEMIC ATTACK	1 (0.30%)	0 (0.00%)
PSYCHIATRIC DISORDERS		
ALCOHOL ABUSE	1 (0.30%)	0 (0.00%)
INSOMNIA	1 (0.30%)	0 (0.00%)
RENAL AND URINARY DISORDERS		
ACUTE KIDNEY INJURY	1 (0.30%)	0 (0.00%)
HAEMATURIA	1 (0.30%)	0 (0.00%)
NEPHROLITHIASIS	1 (0.30%)	0 (0.00%)
URINARY RETENTION	1 (0.30%)	0 (0.00%)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS		
BENIGN PROSTATIC HYPERPLASIA	1 (0.30%)	1 (0.30%)
PROSTATITIS	0 (0.00%)	1 (0.30%)
UTERINE HAEMORRHAGE	0 (0.00%)	1 (0.30%)
RESPIRATORY, THORACIC AND		

MEDIASTINAL DISORDERS		
ALVEOLITIS ALLERGIC	1 (0.30%)	0 (0.00%)
INTERSTITIAL LUNG DISEASE	1 (0.30%)	0 (0.00%)
PULMONARY EMBOLISM	0 (0.00%)	1 (0.30%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		
LICHENIFICATION	1 (0.30%)	0 (0.00%)
PEMPHIGOID	0 (0.00%)	1 (0.30%)
SEGMENTED HYALINISING VASCULITIS	1 (0.30%)	0 (0.00%)
VASCULAR DISORDERS		
AORTIC ANEURYSM RUPTURE	0 (0.00%)	1 (0.30%)
DEEP VEIN THROMBOSIS	0 (0.00%)	1 (0.30%)
VARICOSE VEIN	1 (0.30%)	0 (0.00%)

Other Adverse Events by System Organ Class

Time Frame Adverse events are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All adverse events reported in this record are from date of First Patient First Treatment until Last Patient Last Visit.

Source Vocabulary for Table Default	MedDRA (19.0)
Assessment Type for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	2%

	AIN457 300 mg N = 335	Ustekinumab N = 336
Total participants affected	270 (80.60%)	246 (73.21%)
GASTROINTESTINAL DISORDERS		
ABDOMINAL PAIN	7 (2.09%)	10 (2.98%)
ABDOMINAL PAIN UPPER	12 (3.58%)	6 (1.79%)
DIARRHOEA	22 (6.57%)	24 (7.14%)
DYSPEPSIA	10 (2.99%)	9 (2.68%)
GASTROOESOPHAGEAL REFLUX DISEASE	7 (2.09%)	3 (0.89%)
NAUSEA	12 (3.58%)	10 (2.98%)
TOOTHACHE	12 (3.58%)	10 (2.98%)
VOMITING	15 (4.48%)	7 (2.08%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		
FATIGUE	20 (5.97%)	12 (3.57%)
PYREXIA	14 (4.18%)	8 (2.38%)
INFECTIONS AND INFESTATIONS		
BRONCHITIS	20 (5.97%)	14 (4.17%)
CONJUNCTIVITIS	18 (5.37%)	8 (2.38%)

CYSTITIS	9 (2.69%)	6 (1.79%)
EAR INFECTION	9 (2.69%)	2 (0.60%)
FOLLICULITIS	11 (3.28%)	4 (1.19%)
GASTROENTERITIS	11 (3.28%)	12 (3.57%)
HERPES ZOSTER	1 (0.30%)	10 (2.98%)
INFLUENZA	33 (9.85%)	16 (4.76%)
NASOPHARYNGITIS	96 (28.66%)	87 (25.89%)
ORAL CANDIDIASIS	14 (4.18%)	2 (0.60%)
ORAL HERPES	13 (3.88%)	6 (1.79%)
PHARYNGITIS	10 (2.99%)	12 (3.57%)
RHINITIS	13 (3.88%)	12 (3.57%)
SINUSITIS	12 (3.58%)	9 (2.68%)
TINEA PEDIS	10 (2.99%)	9 (2.68%)
TONSILLITIS	11 (3.28%)	5 (1.49%)
UPPER RESPIRATORY TRACT INFECTION	42 (12.54%)	36 (10.71%)
URINARY TRACT INFECTION	15 (4.48%)	7 (2.08%)
VIRAL UPPER RESPIRATORY TRACT INFECTION	11 (3.28%)	6 (1.79%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		
ARTHROPOD BITE	7 (2.09%)	0 (0.00%)
CONTUSION	7 (2.09%)	8 (2.38%)
LIGAMENT SPRAIN	6 (1.79%)	8 (2.38%)

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		
ARTHRALGIA	36 (10.75%)	33 (9.82%)
BACK PAIN	29 (8.66%)	26 (7.74%)
MUSCULOSKELETAL PAIN	9 (2.69%)	7 (2.08%)
MYALGIA	8 (2.39%)	6 (1.79%)
NECK PAIN	7 (2.09%)	3 (0.89%)
PAIN IN EXTREMITY	11 (3.28%)	11 (3.27%)
PSORIATIC ARTHROPATHY	10 (2.99%)	11 (3.27%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		
SKIN PAPILLOMA	7 (2.09%)	4 (1.19%)
NERVOUS SYSTEM DISORDERS		
HEADACHE	50 (14.93%)	46 (13.69%)
PSYCHIATRIC DISORDERS		
ANXIETY	9 (2.69%)	3 (0.89%)
DEPRESSION	6 (1.79%)	9 (2.68%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		
COUGH	21 (6.27%)	20 (5.95%)
OROPHARYNGEAL PAIN	32 (9.55%)	18 (5.36%)
RHINORRHOEA	7 (2.09%)	6 (1.79%)

SKIN AND SUBCUTANEOUS TISSUE DISORDERS		
DRY SKIN	7 (2.09%)	4 (1.19%)
ECZEMA	19 (5.67%)	12 (3.57%)
PRURITUS	25 (7.46%)	28 (8.33%)
PRURITUS GENERALISED	8 (2.39%)	8 (2.38%)
PSORIASIS	22 (6.57%)	21 (6.25%)
SEBORRHOEIC DERMATITIS	9 (2.69%)	5 (1.49%)
URTICARIA	4 (1.19%)	7 (2.08%)
VASCULAR DISORDERS		
HYPERTENSION	15 (4.48%)	18 (5.36%)

Other Relevant Findings

Conclusion:

PASI 90 response at Week 16: Superior efficacy was observed for secukinumab vs. ustekinumab with respect to the primary endpoint of PASI 90 response at Week 16 (79.0% of patients on secukinumab vs. 57.3% of patients on ustekinumab, OR=2.85, 95% CI: 2.01, 4.02, p<0.0001).
Speed of onset: Superior efficacy was observed for secukinumab vs. ustekinumab with respect to PASI 75 response at Week 4 (49.7% vs. 20.6%). The odds ratio estimate in favor of secukinumab (3.81, 95% CI: 2.71, 5.35) in PASI 75 response at Week 4, was clinically relevant and statistically significant (p<0.0001).

PASI 90 response at Week 52: Superior efficacy was observed for secukinumab vs. ustekinumab with respect to PASI 90 response at Week 52 (74.9% vs. 60.6%). The odds ratio estimate in favor of secukinumab (1.93, 95% CI: 1.39, 2.70) in PASI 90 response at Week 52, was clinically relevant and statistically significant (p=0.0001).

Date of Clinical Trial Report

13-Feb-2017